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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/888,824

06/25/2001

Eric Perrier

5219 US

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7590

08/01/2011

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1653

MAIL DATE

DELIVERY MODE

08/01/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/888,824	Applicant(s) PERRIER ET AL.
	Examiner SUSAN HANLEY	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70,72-78,82-86,91,96, 98-100 and 103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91 and 103 is/are allowed.
- 6) ☒ Claim(s) 70,72-78,82-86,96 and 98-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/2011 and 6/7/2011 has been entered.

Claims 70, 72-78, 82-86, 91, 96, 98-100 and 103 are under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 70, 72, 76, 78, 82, 85, 86, 96 and 98-100 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comai et al. (US 4,218,443; cited in the IDS filed 8/31/04) in view of Guegler et al. (US 2002/0052034), Nozaki et al. (1984), Taber's Medical Dictionary and Wang et al. (cited in the Office action of 4/1/06).

Applicant argues that claims 70, 99 and 100 claim "a fatty acid-acceptor substance or fatty acid sequestering substance which avoids or limits the blockage of enzyme activity of the lipoprotein lipase for a period of time sufficient for releasing at least a part of non-esterified fatty acid from the triacylglycerol".

Applicants assert that in the rejection, Guegler is cited for the teaching of establishing that lipase, and lipoprotein lipase are central to lipolysis and control the

balance of free fatty acids in adipose tissue. Applicants state that as described in the present application, inhibitors are "described in the scientific literature for being inhibitors which act by competition with the substrate of the enzyme." Applicants argue that Guegler is no different, teaching in paragraph [0067] of the published application that "[t]hat, proteins of the present invention are also useful in competition binding assays." Applicants assert that the claimed invention blocks competition. That is the claimed invention "avoids or limits the blockage of the enzymatic activity." Applicants argue that Guegler uses competition binding assays; that is, the blockage of a competition, essentially as claimed, would render Guegler unsuitable of the stated intended purpose. Applicants conclude that the proposed combination of Guegler together fails to teach or suggest the claimed invention of avoiding or limiting the blockage of the enzymatic activity of the lipoprotein lipase.

Applicant's argument has been considered but it is not persuasive. Claim 70 is directed to "a method for identifying a compound or extract for manufacturing a topical composition for inhibiting lipoprotein lipase (LPL) thereby limiting uptake of fatty acids by adipocytes". Claims 99 and 100 recite "determining the capacity of inhibition of the release of substrate of non-esterified fatty acid resulting from the activity of the lipoprotein lipase". The specification at page 4 teaches that the invention makes use of any substance that "in particular is capable of inhibiting the activity of lipoprotein lipase as a novel means of action for limiting the storage in the adipocytes" (lines 18-22). Thus, the invention is drawn to a method of determining inhibitors of LPL since inhibition of LPL will limit the uptake of fatty acids by the adipocytes which will prevent them to be

stored again in the form of triacylglycerols (specification, page 4, lines 8-14). Figures 1-3 show the inhibition of LPL as a function of the concentration of liana extract, *Uncaria tomentosa* extract and St. John's wort.

There is no disclosure in the specification that teaches that the claimed invention is directed to blocking the inhibition of LPL. That would be counter-intuitive to the stated purpose of the invention which is to limited fatty acid uptake by adipocytes. Inhibiting LPL prevents the formation of fatty acids which can be absorbed by adipocytes.

It appears that Applicants are confusing the intention of "a fatty acid-acceptor substance or fatty acid sequestering substance which avoids or limits the blockage of enzyme activity of the lipoprotein lipase for a period of time sufficient for releasing at least a part of non-esterified fatty acid from the triacylglycerol". The purpose of the sequestering substance is to bind the product of the lipolytic reaction (non-esterified fatty acids) so that the fatty acid products do not block the lipoprotein lipase reaction (e.g., preventing feedback inhibition of the product of the reaction from inhibiting the forward progress of the reaction). Thus, the claimed assay is concerned with finding inhibitors of lipoprotein lipase and Guegler is appropriate to the rejection since Guegler establishes that lipases, and lipoprotein lipase in particular, are central to lipolysis and control the balance of free fatty acids in adipose tissue (section 006-009). Guegler teaches that agents that modulate lipases can be identified using cell-based or cell free system first and then confirm activity in an animal or other model system. Such model systems are well known in the art and can readily be employed in this context (section

0067). Modulators of lipase protein activity identified according to these drug screening assays can be used to treat a subject with a disorder mediated by the lipase pathway by treating cells or tissues that express the lipase (section 0066).

Regarding Applicants argument that Guegler is concerned with competition binding assays, that is what Applicants are claiming. That is, a method to determine inhibitors of lipoprotein lipase wherein a compound or extract competes with the triacylglycerol substrate to inhibit the LPL so that it will not produce non-esterified fatty acids.

Claims 70, 72, 76-78, 82, 85, 86, 96, and 98-100 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comai et al. (US 4,218,443; cited in the IDS filed 8/31/04) in view of Guegler et al. (US 2002/0052034, Nozaki et al. (1984), Taber's Medical Dictionary and Wang et al., as applied to claims 70, 72, 76, 78, 82, 85, 86, 96 and 98-100, in further view of Vanio et al. (1982; "Vanio").

Applicant reiterates the argument regarding Guegler and that the combination of references fails to overcome the deficiencies of Guegler.

As noted supra, the stated aim of the invention in the claims and the specification is to inhibit the activity of LPL thereby decreasing the amount of fatty acids in the body which in turns limits the amount of fatty acids that can be taken up by adipocytes. Hence, Guegler's disclosure of competitive inhibitors of LPL is relevant to the invention. Vanio was cited to discloses that LPL requires apoC-II colipase for maximal activity.

Claims 70, 72-78, 82-86, 96, and 98-100 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Comai et al. (US 4,218,443; cited in the IDS filed 8/31/04) in view of Guegler et al. (US 2002/0052034), Nozaki et al. (1984), Taber's Medical Dictionary, Wang et al., and Vanio et al. (1982), as applied to claims 70, 72, 76-78, 82, 85, 86, 96, and 98-100, in further view of Kobayashi (US 3,875,007).

Applicant reiterates the argument regarding Guegler and that the combination of references fails to overcome the deficiencies of Guegler.

As noted supra, the stated aim of the invention in the claims and the specification is to inhibit the activity of LPL thereby decreasing the amount of fatty acids in the body which in turns limits the amount of fatty acids that can be taken up by adipocytes. Hence, Guegler's disclosure of competitive inhibitors of LPL is relevant to the invention. Kobayashi was cited to disclose that the lipolytic activity of a substance designated as GA-56 was established, in part, by comparing the activity of known inhibitors of LPL on its activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on 571-272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susan Hanley/
Primary Examiner, Art Unit 1653